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EXAMINER

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Paper No. 34

Application Number: 09/077,194
Filing Date: December 04, 1998
Appellant(s): BOHN ET AL.

Jeremy M. Stipkala
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed December 16, 2002.

(1) *Real Party in Interest*

A statement identifying the real party in interest, Aventis Pharma Deutschland GmbH, is contained in the brief.

(2) *Related Appeals and Interferences*

The brief does not contain a statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the

decision in the pending appeal is contained in the brief. Therefore, it is presumed that there are none. The Board, however, may exercise its discretion to require an explicit statement as to the existence of any related appeals and interferences.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct in noting that the amendment filed December 16, 2002 to correct minor errors. Amendment is properly entered, thus the reader is directed to Appendix B for the claims on appeal.

(5) Summary of Invention

The summary of invention contained in the brief is deficient because appellants claim an effective treatment for seborrheic dermatitis using a composition comprising an effective amount of compound(s) known as 1-hydroxy-2-pyridones, but not limited to a shampoo composition (see independent claims 38, 53, 59, 65, etc). Appellants claims are not necessarily limited by weakly acidic pH environment(see claim 39, 59, 66, etc).

In respect to the statement (see at page 3, lines 5-8, appellants brief) where appellants claim their invention is different from the conventional treatment because appellants invention is featuring a composition rinsed away as with a shampoo whereas the conventional treatment is remained on the affected skin, appellants fail to claim the said features in the instant claims wherein the claims are drawn to a method for treating seborrheic dermatitis comprising administering a composition having 1-hydroxy-2-

pyridone compounds , surfactant, and optionally keratolytic agent. Therefore, it is considered to be that the instant claims fail to include all the inventive subject matter as recited in the brief.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The appellant's statement regarding grouping of claims in the brief is correct.

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

5,132,107	Lange	07-1992
5,650,145	Saint-Leger	07-1997
4,699,924	Durrant et al.	10-1987

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 39-42, 48 and 53-66 are rejected under 35 U.S.C. 103(a). In previous office action, there is a typographical error found wherein 102(b) is included in the page 2. However, this error is made inadvertently and should be ignored because the title and context are clearly stating that the rejection is based on a 103(a) rejection which is not anticipated but obvious over the prior art of the record.

This rejection is summarized as follows:

1. Claims 38-39, 41-42, 48, 53-54 and 56-66 are rejected under 35 U.S.C. 103(a) as being obvious over Lange(US 5,132,107) alone, if necessary, in view of Durrant et al(US 4,699,924).

Lange teaches a shampoo composition having two phases wherein the first phase(I) includes a detergent and the second phase(II) includes an antimycotic in weakly acidic environment, see abstract. At column 5, lines 15-65, the phase II has pH of 3-6, preferred 4-5 and contains an effective antimycotic compound(i.e. piroctone olamine) because of its anti-seborrheic effect. It further teaches that it can be combined with beneficial additives such as zinc pyridithione, sulfur agent, salicylic acid or lactic acid, see column 4, lines 54 or column 5, lines 27-32. It is well known in the art that these said additives (e.g. zinc pyridithione, selenium sulfide, salicylic acid) are acting as have keratolytic agents.

Lange also teaches that weakly acidic phase II may include piroctone olamine as an active component (see column 5, lines 64-65) and a small amount of quaternary ammonium compounds("quat") which enhances the retention of the piroctone olamine(1-hydroxy-4-methyl-6-(2,4,4-trimethyl-pentyl)-2-(1H)-pyridinone) on the skin(see column 4, lines 50-51 and column 8, lines 35-38).

Lange teaches that the said combination of phase I and phase II results in synergy wherein the therapeutic effects of phase II is enhanced by phase I. Claim 39 requires a method of treating seborrheic dermatitis using the a composition comprising at least one 1-hydroxy-2-pyrone of formula I and a surfactant. Claim 41 requires 1-

Art Unit: 1614

hydroxy-2-pyrone with octyl radical which is the compound taught by the cited reference(i.e. piroctone olamine). Claims 53-66 require an addition of keratolytic agent such as sulfur or salicylic acid, or lactic acid.

Applicant's claims differ because Lange fails to contemplate a example having all the critical elements whereas Lange's suggestion includes all the critical elements for formulating a pharmaceutically effective composition.

Even though Lange does not express the term "surfactant", it would have been obvious, however, to one of ordinary skill in the art that "quat" is surfactant. Thus, one would have been motivate to modify Lange's teaching to make a composition comprising first phase having detergent(often known as surfactant) and second phases having a piroctone olamine as an active antimycotic agent for anti-seborrheic effect, a surfactant for enhance the therapeutic efficacy by improving the skin retention and a keratolytic agent to add extra benefit into the said composition for both cleaning and therapeutic purpose. Or, one would have been motivated to make a phase II composition(as a separate composition) comprising a piroctone olamine as an active antimycotic agent for anti-seborrheic effect, a surfactant for enhance the therapeutic efficacy by improving the skin retention and a keratolytic agent to add extra benefit into the said composition for specifically treating seborrheic dermatitis. One would have been motivated to do, with reasonable expectation of success, because the techniques for combining these well known components are considered to be conventional knowledge and well within the skilled level of artisan having ordinary skill.

In any event, Durrant teaches a antidandruff cream consisting essentially of OCTOPIROX as an active agent and surfactant(i.e. EMULSENE 1219). The pH of Durrant's patented composition could be adjusted, for example, to pH 4.5 with triethanolamine, see column 14, lines 50. Thus one would have been motivated to make an antidandruff composition useful in seborrheic dermatitis consisting essentially of (or comprising) at least antimycotic agent 1-hydroxy-2-pyrone of formula I and one or more surfactant(s) wherein the composition has pH ranged from 4.5-6.5, to increase the therapeutic effects because the antiseborrheic effect could be maximized after cleansing the skin and the combining this ingredients in one composition is well within the skilled level of the artisan having ordinary skill in the art, as evidenced by the Durrant. One would have been motivated to do so to make the cost-effective product when it combines in one product and improve the compliance that leads to higher therapeutic effects. Especially as suggested in Lange(at column 6, lines 45-47), the second phase composition is packaged separately from the first phase composition and the method of treating seborrheic dermatitis could be achieved regardless the first phase composition, especially could be achieved by any cleansing activity in daily life.

2. Claims 40 and 55 are rejected under 35 U.S.C. 103(a) as being obvious over Lange(US 5,132,107) and Durrant et al(US 4,699,924), in further in view of Saint-Leger(US 5,650,145).

Claims 40 and 55 require 1-hydroxy-2-pyridone with cyclohexyl radical substitution in R4 position. Saint-Leger teaches that Octopirox or Ciclopirox is effectively used in the treatment of seborrheic dermatitis(see column 2, lines 29-32).

Thus, it would have been obvious to one of ordinary skill in the art to substitute one to another as suggested by Saint-Leger. One would have motivated to so for better selection or accessibility, and to fit in one's preference.

One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same (or similar) ingredients and share common utilities, and pertinent to the problem which applicant is concerning. MPEP 2141.01(a).

(11) *Response to Argument*

In respect to the appellants' statement regarding this examiner's admission during the interview, this examiner would like to clarify that the said admission is agreed conditionally on the basis that appellants invention is consisting of one phase composition. Appellents' argument during the interview was about that Lange's two phase composition can't be feasible and different from appellents' one phase composition . This examiner has only admitted the defect under the condition described above. As discussed during the interview, the instant claims fail to include the said features described immediately above(i.e. one phase composition). The instant claim 38 is drawn to a method of treating seborrheic dermatitis comprising administering a composition comprising an active component consisting essentially of at least one 1-hydroxy-2 pyridone of formula I. Since the instant claims are not amended to include the said feature, this examiner's admission, thus, is not valid in this case.

Even if this examiner's admission regarding the deficiency found in Lange, this examiner's rejection is not based on 102 rejection but 103 rejection wherein this

examiner acknowledged that Lange has the defect which can be remedied by conventionally wisdom. Therefore, appellant's claims are not patentable over Lange alone.

As mentioned immediately above (*supra*), Lange teaches a shampoo composition containing two phases separately or combined in one package, see column 6, lines 39-42. First of all, as recited in the instant claims, appellents' claims using the open ending term (i.e. "comprising") wherein appellant's composition comprising an active component consisting essentially of at least one 1-hydroxy-2-pyridone of formula I. It is noted that the instant claims are not requiring a composition consisting essentially of 1-hydroxy-2-pyridone of formula I with pH 4.5-6.5 but an active component consisting essentially 1-hydroxy-2-pyridone. Thus, this broadly drafted instant claims are encompassed by the teaching of Lange's reference wherein Lange's patented shampoo composition having two phases, and the said composition comprises phase I with surfactants(e.g. cocoamidopropylbetadine(amphoteric), or triethanolamine laurylsulphate(detergent), see examples) and phase II with antimycotic having anti-seborrheic effect in pH of 3-6(see column 5, lines 34-35).

Even if Lange's composition is consisting of two compositions, one of Lange's two composition suggests all the critical elements. Lange's phase II composition includes antimycotics having anti-seborrheic effect in pH of 3-6(see column 5, lines 34-35). Lange also teaches that weakly acidic phase II may include piroctone olamine as an active component (see column 5, lines 64-65) and a small amount of quaternary ammonium compounds("quat") which enhances the retention of the piroctone

olamine(1-hydroxy-4-methyl-6-(2,4,4-trimethyl-pentyl)-2-(1H)-pyridinone) on the skin(see column 4, lines 50-51and column 8, lines 35-38). Lange also teaches keratolytic agent as beneficial additives such as zinc pyridithione, salicylic acid or lactic acid,see column 4, lines 54 or column 5, lines 27-32. It is well known in the art that zinc pyridithione is keratolytic agent. Thus, one would have been motivated to include a small amount of "quat" into phase II composition to enhance therapeutic efficacy and to treat seborrheic dermatitis as suggested by Lange. It is noted that the instant claims are requiring a surfactant not detergent. Since the instant claims requiring an active component, a surfactant, and pH of 3.5-6.5, all the critical elements are obvious by Lange's suggestion and the claimed subject matter is not patentable over Lange alone. If Lange's composition is used separately, one would have been motivated to use phase II composition to treat seborrheic dermatitis, with reasonable expectation of success, because the phase II composition having active antimycotic component which is responsible for therapeutic effectiveness, quarternary ammonium compounds(surfactant) and optionally zinc pyridithion, sulfur, salicylic acid or lactic acid to add extra benefits wherein the additives are utilizing different biological pathway so that they could assist the active agent without causing the toxicity but lowering effective dose and reducing undesired side effect.

By having Lange's teaching inview of Durrant, the said deficiencies has been remedied because Durrant teaches antidandruff hair cream composition(single composition). Thus, knowing anti-seborrheic effect from Lange's teaching, one would have been motivated to make a single composition(e.g.hair formulation) having all the

Art Unit: 1614

said critical components in weakly acidic environment to reduce skin irritation while the composition maintains its therapeutic effectiveness from active agents(e.g. antimycotic(pirotone olamine), keratolytic, etc).

By taking Saint-Leger's teaching, the deficiencies required by claims 40 and 55 are remedied because Saint-Leger teaches that Octopirox or Ciclopirox is effectively used in the treatment of seborrheic dermatitis(see column 2, lines 29-32).

Thus, one would have been motivated to make such modification because it is always desired to have more selection option to satisfy patient's needs.


It is noted that the minor variations including the selection of optimal dosages, pH modification, or combination drug therapy with known secondary active additive in order to determine the most effective treatment is well within the skilled level of artisan having ordinary skill in the art, and is obvious. As admitted in the instant specification(at page 9, lines 29-34), the pH modification is adapted to close to skin physiological pH(natural skin pH is weakly acidic) which is conventionally known to be ideal due to less skin irritation. Thus, the said modification is not considered to be particular nor difficult, and is obvious to one of ordinary skill in the art to practice with reasonable expectation of success.

For the above reasons, it is believed that the rejections should be sustained.

Application/Control Number: 09/077,194
Art Unit: 1614

Page 11

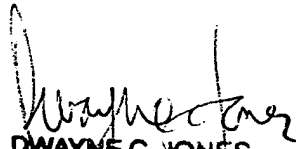
Respectfully submitted,



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